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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, CAMTU TRAN	
ART UNIT	**PAPER NUMBER**
3772	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,195	RACENET ET AL.	
	Examiner	Art Unit	
	Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-9,11,13,17,20 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9,11,13,17,20 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 11/5/2009. Claims 1-4, 10, 12, 14-16, 18-19, 21-31 have been cancelled. Claims 32-36 are newly added.

Response to Arguments

The Objections to the specification has been withdrawn in view of applicant's amendment.

The Objections to the drawings has been withdrawn in view of applicant's remarks.

The 112 rejections presented in the previous Action have been withdrawn in view of applicant's amendment.

Applicant amended claim 5 to now recite a seal clamp.

Applicant added new independent claim 33 particularly reciting the sealing member (218) having a general hourglass shaped segment and an annular segment projecting radially inwardly from the hourglass segment.

Applicant's remarks against the Young reference as acknowledged, in particular, the Young do not teach a seal clamp (newly added), however, the remarks deemed not persuasive in view of the following interpretation.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the annular segment (claims 33 & 36) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 recites the limitation "the longitudinal midpoint" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

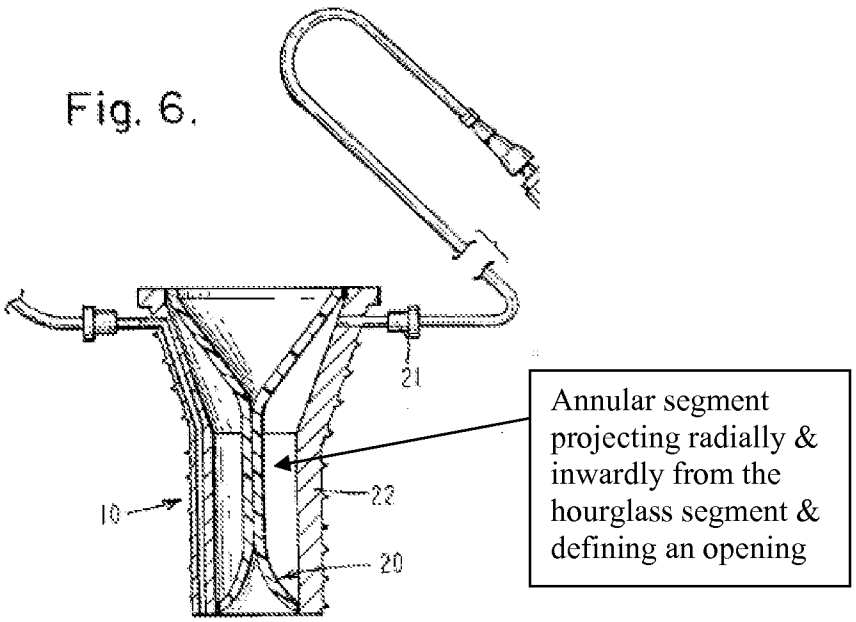
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al (U.S. Patent No. 5,634,937) in view of Stablein (DE 37 37 121 A1).

Mollenauer et al discloses a trocar stabilizer device for accessing to body tissue, the device comprising a housing (10), a cannula member (22) having a longitudinal passage for purposes of receiving an endoscope (34), a sealing member (20) disposed within the housing (10), the sealing member (20) extending across the longitudinal axis of the cannula member (22), and the sealing member (20). The sealing member (20) defining an opening in an initial condition thereof for receipt of the endoscope (34) and arranged so that the insertion of the endoscope (34) causes the opening of the sealing member (20) to expand to an expanded

condition thereof and resiliently contact the outer surface of the endoscope (34) to form a substantially seal therewith.

Figure 6 illustrates the sealing member (20) having a general hourglass shaped segment. Figures 5 &6 illustrates the sealing member (20) having an annular segment and the annular segment defining an opening. See illustration below.



The Mollenauer et al device, however, discloses its seal member (20) is of elastomeric/elastic material instead of fabric material, as required by claims 5 & 33.

Stablein further discloses a sealing system for catheter/instrument insertion assembly, the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material (see last paragraph of column 2).

Therefore, it would have been obvious to one skilled in the art to modify the Mollenauer et al sealing member (20) such that it would include a layer of fabric, as taught by Stablein, for purposes of providing not only flexibility during insertion of the endoscope (34) but also greater resistance, thus, to form a tighter fluidic seal in relation about the endoscope (34).

Regarding claim 35, in the Mollenauer et al/Stablein combination, specifically the Mollenauer's sealing member (20) dimensioned such that the opening expands such that the surfaces of the hourglass segment adjacent the annular segment resiliently contact the outer surface of the instrument (34) to form the substantial seal therewith. See Figure 8.

Regarding claim 36, in the Mollenauer et al/Stablein combination, specifically the Mollenauer's annular segment is disposed adjacent the longitudinal midpoint of the sealing member (20).

Claims 5-9, 20, and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 5,391,154) in view of Stablein (DE 37 37 121 A1).

Young discloses in Figure 2 a cannula assembly (10) comprising a housing (10), a seal member (30) in hourglass shape (column 4 lines 57-63) disposed in the housing (10), the seal member (30) defining a opening (40) to receiving an instrument therein, the seal member (30) is resilient (column 4 lines 66-68, column 5 lines 1-8, column 6 lines 51-62) to accommodate & to provide a fluid seal with instrument(s) of varying diameter. Figure 3 illustrates a cannula member (24) extending across the seal member (30) and having a bore therethrough.

Regarding claim 5 reciting a seal clamp, Figure 4 in the Young reference illustrates a seal clamp (48, 50) secure an outer periphery of the seal member (30) within the housing (10).

Regarding claim 33, Figures 2 & 4 illustrates the seal member (30) having an annular segment (42) projecting radially inward from the hourglass segment (44, 46).

The Young discloses the seal member (30) is of elastomeric material instead of fabric material, as required by claims 5 & 33.

Stablein further discloses a sealing system for catheter/instrument insertion assembly, the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric (see last paragraph of column 2).

Therefore, it would have been obvious to one skilled in the art to modify the Young seal member (30) such that it includes a layer of fabric, as taught by Stablein, as for purpose of providing not only flexibility during insertion of the instrument but also greater resistance, thus, to form a tighter fluidic seal in relation about the instrument.

Regarding claim 6 &7, in the Young/Stablein combination, specifically the Young reference teaches the seal member (30) is fabricated from an elastomeric material such as synthetic/natural rubber, which is resilient (column 7 lines 66-68).

Regarding claim 20, in the Young/Stablein combination, specifically the Young reference teaches the seal member (30) is non-inflatable.

Regarding claim 32, in the Young/Stablein combination, specifically the Young reference teaches the seal member (30) includes a projection (42) extending inwardly into the opening (40) defined by the hourglass shape (44, 46) of the seal member (30), the projection (42) configured/dimensioned to engage the surgical to enhance the seal formed therewith upon insertion.

Regarding claim 34 reciting a seal clamp, in the Young/Stablein combination, specifically the Young reference teaches a seal clamp (48, 50) secure an outer periphery of the seal member (30) within the housing (10).

Regarding claim 35, in the Young/Stablein combination, specifically the Young reference teaches seal member (30) dimensioned such that the opening (40) expands such that the surfaces of the hourglass segment (44, 46) adjacent the annular segment (42) resiliently contact the outer surface of the instrument (34) to form the substantial seal therewith. See Figures 4 & 8.

Regarding claim 36, in the Young/Stablein combination, specifically the Young reference teaches the annular segment (42) is disposed adjacent the longitudinal midpoint of the sealing member (30).

Regarding claims 8, in the Young/Stablein combination, specifically the Young reference teaches the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material. As such, it would have been obvious that the fabric is compressed into the soft/flexible but tear-resistant of natural/synthetic/soft plastic material, by the soft/flexible but tear-resistant of natural/synthetic/soft plastic material disposed within the interstices of the fabric.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 5,391,154)/Stablein (DE 37 37 121 A1), presented above, and further in view of Stephens et al (U.S. Patent No. 5,350,364).

Young/Stablein a cannula assembly (10) comprising all of the elements presented in these claims, as represented above, but does not teach the assembly (10) further comprising a zero seal in the housing.

Stephens et al discloses a trocar assembly (10) comprising a zero seal in the form of a flapper valve (164).

Therefore, it would have been obvious to one skilled in the art to modify the Young/Stablein cannula assembly (10) to include a flapper valve (164), taught by Stephens as such would substantially inhibit escape of insufflation gases absent of an instrument.

Claims 11 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 5,391,154)/Stablein (DE 37 37 121 A1), presented above, and further in view of Hu (U.S. Patent No. 5,463,010).

Young/Stablein discloses a cannula assembly (10) comprising all of the elements presented in these claims, as represented above, but does not teach the seal member (30) to include a coating of material for reducing friction between the seal member and an instrument inserted through the seal member.

Hu discloses and teaches the hydrocyclosiloxane membrane, a coating material for reducing friction between the seal member and the instrument used through the seal member.

Therefore, it would have been obvious to one of ordinary skill in the art to have a coating material applied onto the Young/Stablein's sealing member, as taught by Hu, as such would not only protect biomedical device but also provide lubrication when the instrument is inserted through seal member.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772